



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gerianne Tringali DiPiano and Peter Kevin Mays

Serial No.: 10/751,056

Art Unit: Not Yet Assigned

Filed: January 2, 2004

Examiner: Not Yet Assigned

For: *PHARMACEUTICAL PREPARATIONS FOR TREATMENTS OF DISEASES AND DISORDERS OF THE BREAST*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including two (2) pages of Form PTO-1449 and copies of fourteen (14) documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

Publications

FENTIMAN, et al., "Dosage and duration of tamoxifen treatment for mastalgia: a controlled trial," *Br J Surg.* 75(9): 845-846 (1988).

FENTIMAN, et al., "Studies of tamoxifen in women with mastalgia," *Br. J. Clinical Prac. Sympt.* 68: 34-36 (1989).

HINTON, et al., "A double-blind controlled trial of danazol and bromocriptine in the management of severe cyclical breast pain," *Br. J. Clin. Practice* 40(8): 326-330 (1986).

HOLLAND & GATELEY, "Drug therapy of mastalgia. What are the options?" *Drugs* 48(5): 709-716 (1994).

IRVIN & MORRISON, "Effectiveness of topical non-steroidal anti-inflammatory drugs in the management of breast pain," *J. R. Coll. Edinb.* 43(3): 158-159 (1998).

LEONARD, et al., "Randomized, double-blind, placebo-controlled, multicenter trial of 6% miltefosine solution, a topical chemotherapy in cutaneous metastases from breast cancer," *J. Clin. Oncol.* 19: 4150-4159 (2001).

MANSEL & DOGLIOTTI, "European multicentre trial of bromocriptine in cyclical mastalgia," *Lancet* 335(868): 190-193 (1990).

MANSEL, et al., "A double blind trial of the prolactin inhibitor bromocriptine in painful benign breast disease," *Br. J. Surgery* 65(10): 724-27 (1978).

MANSEL, et al., "Controlled trial of the antigonadotropin danazol in painful nodular benign breast disease," *Lancet* 1(8278): 928-933 (1982).

MILLET & DIRBAS, "Clinical management of breast pain: a review," *Obstet. Gynecol. Survey* 57(7): 451-461 (2002).

NAZLI, et al., "Controlled trial of the prolactin inhibitor bromocriptine (Parlodel) in the treatment of severe cyclical mastalgia," *Br J Clin Pract* 43: 322-327 (1989).

STEINBRUNN, et al., "Mastalgia. Tailoring treatment to type of breast pain," *Postgraduate Medicine* 102(5): 183-184; 187-187; 193-194 (1997).

TERWOGT, et al., "Phase II trial of topically applied miltefosine solution in patients with skin-metastasized breast cancer," *Br. J. Cancer* 79: 1158-1161 (1999).

UNGER, et al., "Hexadecylphosphocholine in the topical treatment of skin metastases in breast cancer patients," *Cancer Treat. Rev.* 17: 243-246 (1990).

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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'P. Pabst', written over a horizontal line.

Patrea L. Pabst
Reg. No. 31,284

Dated: April 8, 2004


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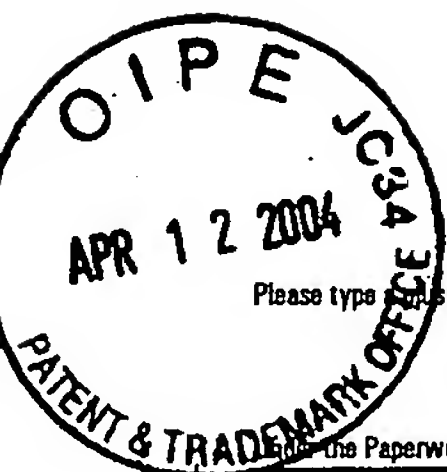
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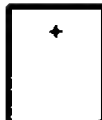
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Erica C. Boughner

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Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/751,056
				Filing Date	January 2, 2004
				First Named Inventor	Gerianne Tringali DiPiano
				Group Art Unit	
				Examiner Name	
Sheet	1	of	2	Attorney Docket Number	FEM 104

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		FENTIMAN, et al., "Dosage and duration of tamoxifen treatment for mastalgia: a controlled trial," <i>Br J Surg</i> , 75(9): 845-846 (1988).	
		FENTIMAN, et al., "Studies of tamoxifen in women with mastalgia," <i>Br. J. Clinical Prac. Sympt.</i> 68: 34-36 (1989).	
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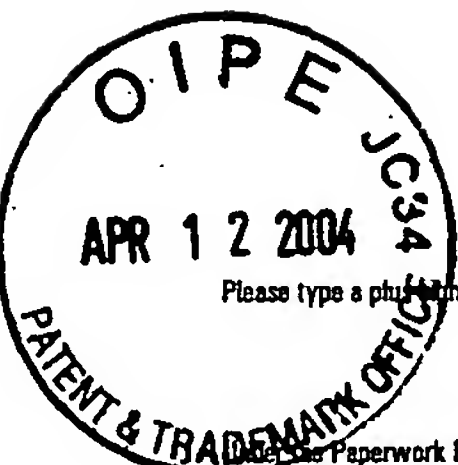
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Attorney Docket Number	FEM 104

Sheet	2	of	2
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